REMARKS

The above amendments and these remarks are responsive to the final Office action dated July 20, 2007 ("Final Office action"). Claims 1–25, 33, and 35–45 are pending in the application. Claims 1–25, 33, and 35–45 are rejected. By way of the present amendment, claim 45 has been amended. In view of the amendments above, and the remarks below, applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Interview on February 7, 2008

As an initial matter, Applicant thanks Examiner Schell for her time during a telephone interview on February 7, 2008. During the interview, Applicant discussed with Examiner Schell the rejections of independent claims 1, 19, and 45 as well as the cited Tom (U.S. Patent No. 7,211,063) and Menne et al. (U.S. Patent No. 5,840,061) references. Applicant discussed with Examiner Schell the extent to which needle-free injection devices were disclosed in the Tom patent. In addition, Applicant discussed with Examiner Schell the annular nature of the fluid channel shown in Figs. 2–4 of the Menne et al. patent in relation to the element of claim 45 that "the fluid channel has a cross section through which the central longitudinal axis extends." In particular, Applicant pointed out that an annular fluid channel would not have a cross section through which its central longitudinal axis extends. Examiner Schell indicated that she would need to discuss the arguments presented during the interview with her supervisor and that she would enter an amendment based on the arguments discussed during the interview as an after-final amendment without requiring Applicant to file an RCE.

Rejections under 35 U.S.C. § 103 : Claims 1–25, 33, and 35–44

Claims 1–25, 33, and 35–44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tom, either alone or variously in view of Glines et al. (US Patent No. 6,716,190) or Paskar (US Patent No. 6,623,449).

Claim 1 and its Dependent Claims

In the Final Office action, the Examiner rejected claim 1 primarily based on Tom. In particular, the Examiner asserted that Tom disclosed, taught, or would have suggested a needle-free jet injection device that includes many of the elements of the needle-free jet injection device recited in claim 1. However, as will be discussed below,

Tom does not disclose, teach, or even suggest many of the elements for which the Examiner cited Tom in the Final Office action.

As an initial matter, Applicant respectfully points out that the device shown in Fig. 1 of Tom (reproduced below) is not a needle-free jet injection device. Rather, Tom discloses a pressure sensor for a therapeutic delivery device. As shown in Fig. 1 and generally described at column 2, line 65 to column 3, line 34, Tom discloses an apparatus 44 for accessing a patient's tissue or organ region 47. The apparatus 44 includes a rigid shaft 46, which may have a curved section, a sensor device 20, and a handle 48. As shown in Fig. 2, the force contact transducer or sensor device 20 includes a cap 30 and a bio-compatible coating or cover 40. The force contact transducer or sensor device 20 is desirably sealed to "prevent ingress of bodily or other fluids into the electrical regions of the apparatus" (column 4, lines 53–55). The cover 40 also "prevent[s] fluid ingress" (column 5, lines 13–16).

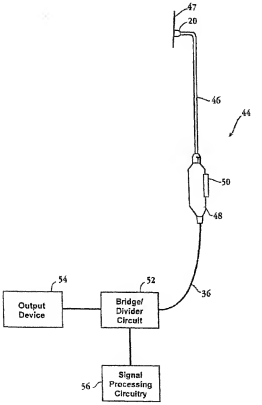


Fig. 1

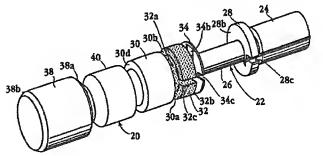


Fig. 2

As described at column 3, lines 35–48 of Tom, "handle 48 may be designed to

produce a selected therapeutic effect on target tissue, when a desired pressure and/or pressure contact angle is sensed between the probe and target tissue." In particular and as cited by the Examiner in the Final Office action, the "therapeutic effect may be, for example, the injection, by a needle or needleless injection system" (column 3, lines 38–39). However, Tom does not disclose any structures or details of such a "needleless injection system." Rather, at column 3, lines 44–48, Tom merely makes a vague general reference that the "apparatus may therefore be equipped, according to well-known devices, to provide an extendable needle, a light fiber, an extendable mechanical-injury device, or the like to produce the desired therapeutic effect, in response to a signal applied by the user to handle 48." The mere naming of a "needleless injection system" and a vague general reference to an apparatus "equipped, according to well-known devices" does not disclose, teach or suggest any structures or details regarding those devices.

Claim 1 recites a needle-free jet injection device for delivering a fluid into an internal organ. The needle-free jet injection device of claim 1 comprises:

> a rigid end effector having a blunt distal end and a longitudinal axis configured into a shape and including a plurality of orifices, the end effector including a rigid interior wall that defines a rigid fluid channel, where the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use, where the fluid channel has a cross section through which a central axis of the end effector extends, and where the end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices;
>
> a fluid reservoir in fluid communication with the end effector; and
>
> an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the orifices with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ and without penetration of the outer surface of the organ by the end effector, where the end effector extends away from the ejection mechanism such that an operative end of the end effector is spaced from the ejection mechanism.

Contrary to the Examiner's assertions in the Final Office action, Tom does not disclose, teach, or even suggest many of the elements of the needle-free jet injection device of claim 1.

Tom does not disclose, teach, or even suggest a rigid end effector as recited in claim 1, which includes:

> a blunt distal end and a longitudinal axis configured into a shape and including a plurality of orifices, the end effector including a rigid interior wall that defines a rigid fluid channel, where the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use, where the fluid channel has a cross section through which a central axis of the end effector extends, and where the end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices.

In particular, Tom does not disclose, teach, or even suggest many of these elements. For example, other than the aforementioned vague general reference to a "needleless injection system," Tom does not disclose, teach, or suggest even a single orifice. In addition, Tom does not disclose, teach, or even suggest a rigid interior wall that defines a rigid fluid channel. Further, because Tom does not disclose, teach, or even suggest a fluid channel, Tom cannot and does not disclose, teach, or even suggest that the fluid channel has a cross section through which a central axis of the end effector extends. Further, because Tom does not disclose, teach, or even suggest an orifice or a fluid channel, Tom cannot and does not disclose, teach, or even suggest that an end effector is configured to enable fluid to flow from the fluid channel out through the plurality of orifices.

Furthermore, Applicant respectfully points out that Tom teaches away from a modification or combination of the pressure sensor disclosed therein to include a plurality of orifices because, as noted above, the sensor is desirably sealed to "prevent ingress of bodily or other fluids into the electrical regions of the apparatus." The modification of the pressure sensor of Tom to include even a single orifice would disrupt any seal and would undesirably permit ingress of bodily or other fluids into the electrical regions of the apparatus, which could render the sensor inoperative or otherwise unsatisfactory for its intended purpose.

Tom does not disclose, teach, or even suggest a needle-free jet injection device that includes a fluid reservoir in fluid communication with the end effector. As noted above, Tom does not disclose, teach, or even suggest an end effector with which a fluid reservoir could be in communication. Furthermore, the ambiguous reference in Tom to a "needleless injection system" that may be "equipped, according to well-known devices" does not disclose, teach, or even suggest a needle-free jet injection device that

includes a fluid reservoir.

Tom does not disclose, teach, or even suggest an ejection mechanism, let alone an ejection mechanism as recited in claim 1, which is adapted to eject the fluid from the fluid reservoir through the end effector and out of the orifices with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ. As noted above, Tom does not disclose, teach, or even suggest a fluid reservoir from which, or orifices through which, fluid may be ejected. The ambiguous reference in Tom to a "needleless injection system" that may be "equipped, according to well-known devices" does not disclose, teach, or even suggest ejecting fluid with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ.

Furthermore, the discussion at column 2, lines 1–16 Tom regarding surface treatment and prevention of "perforation type injuries" is wholly irrelevant to ejecting fluid with sufficient pressure to penetrate an outer surface of the organ while preserving functionality of the organ. Rather, the cited discussion was part of the summary of the pressure sensor invention disclosed in Tom, not the "needleless injection system" that is vaguely referenced at column 3, lines 35–48. As described at column 2, lines 1–7, the pressure sensor invention of Tom "provide[s] information to the user of a medical instrument, such as a catheter, that must be placed in contact with the surface of an anatomical structure, to increase the likelihood of safely delivering the desired treatment while reducing the possibility of inflicting perforation type injuries or providing inadequate treatment." In particular, as described at column 2, lines 8–11, the disclosure of Tom is directed toward "generating information regarding whether the tip of a medical instrument, such as a catheter or probe, is in contact with a surface of a tissue or organ, and, if so, the magnitude of the contact force." Information regarding (1) the existence of contact between the tip of a medical instrument and the surface of a tissue or organ or (2) the magnitude of any contact force has no relevance to a particular ejection pressure or pressure range that is sufficient to penetrate an outer surface of the organ while preserving functionality of the organ. Thus, Tom does not disclose, teach, or even suggest an ejection pressure, let alone a pressure sufficient to penetrate an outer surface of the organ while preserving functionality of the organ, as recited in claim 1.

For at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a device as claimed in claim 1. Claims 2–18, 33 and 35–43 depend from claim 1. Claims 2–18, 33 and 35–43, each of which contains further limitations that distinguish the cited references, are thus allowable for at least the reasons stated above with respect to claim 1. Accordingly, claim 1 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 1–18, 33 and 35–43 under 35 U.S.C. § 103 be withdrawn.

Claim 3

Claim 3, which depends from claim 1, recites that at least some of the orifices are located in the distal section. As noted above, Tom does not disclose, teach or suggest orifices, let alone the location of a particular orifice. Thus, for at least these additional reasons, Tom does not disclose, teach or suggest a device as claimed in claim 3. Claim 4 depends from claim 3 and is thus allowable for at least the reasons stated above with respect to claim 3. Accordingly, claim 3 and 4 patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 3 and 4 under 35 U.S.C. § 103 be withdrawn.

Claim 6

Claim 6, which depends from claim 1, recites that "the pressure with which the fluid is ejected through the orifice is sufficient to cause a transmural lesion in the organ." As described at lines 2–4 on page 9 of the specification of the present application, transmural refers to fluid penetration throughout the entire wall thickness of an organ. Furthermore, the Free Online Medical Dictionary, Thesaurus and Encyclopedia defines transmural as "extending through or affecting the entire thickness of a wall of an organ or cavity" (http://medical-dictionary.thefreedictionary.com/transmural). In contrast, the portions of Tom cited by the Examiner (i.e., the abstract, column 1, lines 16–61, and column 2, lines 1–7) at most disclose that the pressure sensor invention of Tom may be used to provide contact information while treating the wall of the heart, with the contact information being usable to avoid perforation of the organ wall. However, such disclosure is wholly irrelevant to whether a needle-free jet injection device causes a transmural lesion in an organ. Thus, Tom does not disclose, teach, or even suggest

causing a transmural lesion in an organ.

Furthermore, as noted above, Tom does not disclose, teach, or even suggest an ejection pressure. Thus, Tom cannot and does not disclose, teach, or even suggest an ejection pressure sufficient to cause a transmural lesion in an organ.

For at least these additional reasons, Tom does not disclose, teach or suggest a device as claimed in claim 6. Claims 7–9 depend from claim 6 and are thus allowable for at least the reasons stated above with respect to claim 6. Accordingly, claim 6 and the claims dependent therefrom patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 6–9 under 35 U.S.C. § 103 be withdrawn.

Claim 33

Claim 33, which depends from claim 1, recites that the fluid channel is cylindrical. As noted above, Tom does not disclose, teach, or even suggest a fluid channel. Thus, Tom cannot and does not disclose, teach, or even suggest that the fluid channel is cylindrical. For at least this additional reason, Tom does not disclose, teach or suggest a device as claimed in claim 33. Accordingly, claim 33 patentably distinguishes the cited art, and Applicant respectfully requests that the rejections of claim 33 under 35 U.S.C. § 103 be withdrawn.

Claim 19 and its Dependent Claims

Claim 19 recites an end effector for a needle-free injection device adapted to inject a fluid through an outer surface of an internal organ and into the internal organ, without penetration of the outer surface of the internal organ by the end effector and while maintaining functionality of the organ. The end effector of claim 19 comprises:

> a longitudinally rigid elongate shaft that extends away from the injection device to a blunt distal end and that includes a tubular fluid channel fluidly and directly coupled with a plurality of orifices through which the fluid may be ejected, wherein the elongate shaft is sufficiently rigid to maintain a longitudinal shape during use, where the tubular fluid channel has a cross section through which a central axis of the end effector extends, and where the tubular fluid channel includes a rigid portion extending substantially all the way between the injection device and the plurality of orifices.

Contrary to the Examiner's assertions in the Final Office action, Tom does not disclose, teach, or even suggest many of these elements. For example, as noted above, Tom

does not disclose, teach, or even suggest any orifices. Rather, as noted above, Tom teaches away from a modification or combination that includes any orifices. In addition, because Tom does not disclose, teach, or even suggest any orifices, Tom cannot and does not disclose, teach, or even suggest a tubular fluid channel, let alone a tubular fluid channel that is fluidly and directly coupled with a plurality of orifices through which the fluid may be ejected. Further, because Tom does not disclose, teach, or even suggest a tubular fluid channel or any orifices, Tom cannot and does not disclose, teach, or even suggest that the tubular fluid channel has a cross section through which a central axis of an end effector extends or that the tubular fluid channel includes a rigid portion extending substantially all the way between the injection device and the plurality of orifices.

Thus, for at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest an end effector as claimed in amended claim 19. Claims 20–25 and 44 depend from claim 19. Claims 20–25 and 44, each of which contains further limitations that distinguish the cited references, are thus allowable for at least the reasons stated above with respect to claim 19. Accordingly, amended claim 19 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 19–25 and 44 under 35 U.S.C. § 103 be withdrawn.

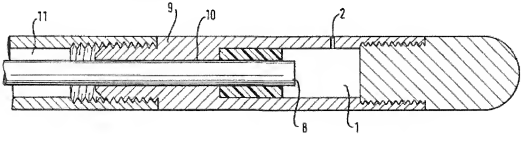
Rejection under 35 U.S.C. § 103 : Claim 45

Claim 45 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. in view of Tom. Applicant disagrees with the rejection. However, Applicant has nonetheless made certain claim amendments to clarify what Applicant regards as his invention based on the discussion during the February 7, 2008 interview regarding the relationship between an annular fluid channel and a central longitudinal axis. In particular, Applicant has amended claim 45 to recite, amongst other structure, a longitudinally rigid elongate member that includes a central longitudinal axis and "a fluid channel extending substantially all the way from the body to the at least one injection orifice, wherein the central longitudinal axis is within the fluid in the fluid channel." Although Applicant believes that the original language of claim 45 (i.e., that the fluid channel has a cross section through which the central longitudinal axis extends) carried

such meaning, Applicant has amended the claims in the hope of advancing prosecution.

Menne et al. does not disclose a fluid channel extending substantially all the way from the body to the at least one injection orifice, wherein the central longitudinal axis is within the fluid in the fluid channel. Rather, as discussed during the February 7, 2008 interview, Applicant respectfully points out that Menne et al. discloses an annular fluid channel through which the longitudinal axis does not pass. As shown in Fig. 2 of Menne et al. (reproduced below), the distal end of a driving piston or probe 8 delimits a pressure chamber 1 that contains liquid flowing into an ejection opening 2 (column 4, lines 56–62). A "narrow liquid flow-through slit 10" remains between the probe 8 and the guiding member 9 where the probe 8 passes through the guiding member 9, with the liquid flow-through slit 10 running "into a liquid supply channel 11 surrounding the probe 8" (column 5, lines 3–8). As discussed during the February 7, 2008 interview, the probe 8 is solid, such that the liquid flow-through slit 10 and liquid supply channel 11 are thus annular fluid channels. As shown in Fig. 2 of Menne et al., the annular liquid flow-through slit 10 and liquid supply channel 11 are both approximately centered relative to the guiding member 9 such that a central longitudinal axis of the guiding member 9 would not be within the fluid in the fluid channel (i.e., the liquid flow-through slit 10 and the liquid supply channel 11), as recited in claim 45. Rather, the central longitudinal axis of the guiding member 9 would be within the probe 8.

Fig. 2



Thus, for at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a needle-free jet injection device as claimed in claim 45. Accordingly, claim 45 patentably distinguishes the cited art, and Applicant respectfully requests that the rejection of claim 45 under 35 U.S.C. § 103 be withdrawn.

Conclusion

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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